



How to deal with an immoral economy? When the Threshold's politics fails

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*How to deal with an immoral economy? When the Threshold's politics fails
The Case of the Cancer Drug Funds in United Kingdom*

“The English have made a decision. They have a relatively strict health care system and they have decided that some drugs’ prices were excessively high regarding their effectiveness. So they have decided to stop the reimbursement of a dozen of these drugs. We use these drugs in France and they’re useful. I don’t want to tell you their names but there are really important and famous drugs”.

Jean-Paul Vernant¹ is a French oncologist who works in the prestigious Parisian hospital La Pitié-Salpêtrière. In March 2016 he is invited to take part to a television talk show. Few days before he published an article in *Le Figaro* with more than hundred others oncologists to denounce the unjustified price of new cancer drugs². In front of the camera, he repeats what he says in this article: the social security won’t be able to finance the new treatments against cancer if their prices don’t diminish. As in the article he also points out that the British system has opted for a different model: a “relatively strict” cost effectiveness based health care system. Of course, in his understanding, this statement implies the idea of an unfair system. Most of time, British Health Care System is indeed perceived as a “liberal” system in which access to treatment must be justified in terms of costs. This representation is especially embedded in the efficiency calculation through the cost per Qalys³ method that I will present further. Nevertheless a very specific entity seems to contradict this view of the British health care system. It has been created in 2011 to pay drugs against cancer that are not cost-effective: the Cancer Drugs Fund. This communication aims to question the functioning of this Fund and to think about its political meaning in a system driven by principles it tends to put into question.

Health care systems in Western countries are nowadays confronted with multiple difficulties that put into question their solvability and their durability (Schäfer, Streeck, 2013). One of these challenges is their capacity to provide effective and efficient care to the population despite the crisis of public finances and the evolution of health problems. The question of the efficiency and effectiveness of treatments for chronic diseases is presented as central for the future, in terms of public health but also in terms of public finances. The expenditures related to patients suffering from chronic diseases are identified as a crucial

¹ Intervention on television, March 2016 (our translation).

² Dominique Maraninchi et Jean-Paul Vernant, « L’urgence de maîtriser les prix des nouveaux médicaments contre le cancer », *Le Figaro*, 15 mars 2016.

³ Quality Adjusted Life Years.

issue for health economics and public authorities⁴. Many kinds of these chronic diseases can be mentioned: chronic kidney disease, chronic obstructive pulmonary disease, asthma, cancer, diabetes, cystic fibrosis, myopathy, etc. Cancer is one of the most important chronic diseases, both in terms of cost for the health care system and incidence in the population. For example, 331 000 cases of cancer were diagnosed in UK in 2011⁵.

Until the 2000's, surgery, radiotherapy and chemotherapy have been the three kinds of treatment for cancer. Since the middle of the 2000's a new kind of medicine has been developed: the targeted therapy. It consists in specific molecules given to the patient in association with more classical chemotherapy in function of results of genetic tests. Two critics are formulated by now: these drugs have uncertain effects (for the most sceptical actors it has minimal effect on the patient survival) and their "cost" is extremely high. Nevertheless public authorities can today hardly refuse the access to the market to these drugs for two reasons: first, the weak effect of these treatments does not mean that any improvement can be achieved in the future; then, the cost of drugs appears not as a robust argument for denying the access for the patients. Recent innovations in terms of cancer treatments have raised the controversy about their cost in every country that has decided to promote them. It is especially the case in the United Kingdom where every new medicine must be cost-effectiveness. The National Institute for Health and Care Excellence, which does the medico-economic evaluation, has established a threshold for expensive drugs. It consists in balancing the effects of the medicine (calculated in Qalys) and the cost of the drug for the society. For usual medicine, the threshold is £30 000 and £50 000 for cancer drugs. But even this higher threshold is not enough to accept on the market the new cancer drugs that are produced by the pharmaceutical industries.

The English Health Care System has therefore been forced to invent a specific mechanism that tends to create an economic and political exception concerning these drugs that have a usual price around £150 000: The Cancer Drugs Fund. On the website of the *Cancer Research UK*, which is an organization in charge of promoting research and information about cancer, the Cancer Drug Fund's goals are described as follow: "*The aim of the fund is to make it easier for people to get as much treatment as possible*".

My interest in the Cancer Drugs Fund is to explore how health innovations imply new political economy of cancer and how the British State try to render accessible drugs that are extremely expensive. It supposes that the "old State's metrological devices" as costs per Qalys are not able to promote the access to drugs in an effective way. The Cancer Drugs Fund embedded a new composition of the political economy of cancer that is characterized by two aspects: 1) the possibility for the State to renounce to its costs-effective perspective when it appears that drugs are too important; 2) the incapacity of the State to obtain lower prices for these drugs and the necessity to create a specific fund to buy them.

The problem I would like to focus on is the way a national health system structures tools of government (Hood, 1983; Lascoumes, Le Galès, 2004) to conduct its health policies efficiently and the way these tools can be challenged by private actors not directly by putting into question these tools but by render them inoperative to help decision

⁴ A General meeting of the United Nations was organized in 2011 in order to consider the increasing place of chronic diseases: <http://www.un.org/press/fr/2011/AG11138.doc.htm>

⁵ For more precise data: Internet website of Cancer Research UK; « Les cancers en France », 2013, Institut National du Cancer.

makers. First of all I present the usual form of regulation of cancer drugs in United Kingdom and especially the rule of the cost per Qalys threshold (1). This methodology has been put into question recently because of new cancer drugs prices (2) and the NHS has been constrained to create an economical and political exception, namely the Cancer Drugs Fund (3). I propose to conclude this communication by thinking about the meaning of the CDF in terms of public policy as a political exception that illustrates the Welfare State contemporary transformations (4).

1) A culture of efficiency: the NHS and the cost per QALY's threshold

The National Health Service in United Kingdom is one of the most studied healthcare system. The British national health policy is indeed a case study of the transformation of the healthcare sector through the managerial principles. Usually, one distinguishes two kinds of indicators that have been implemented. The first concerns the performance of the hospitals measured by the rate of the occupation of beds, the duration of the stays, the time patients wait before being treated by a physician, etc. The second concerns economic indicators. Many works have for example demonstrated how British hospitals have been converted into economic entities especially with the implementation of the payment by results (Kurunmäki, Miller, 2008)⁶.

One of the leading principle of this transformation has been the “value for money” principle promoted under the Margaret Thatcher’s government. As Patrick Le Galès and Florence Faucher-King have noticed, *“In 1979 the Efficiency Unit and the Scrutiny Program are created and attached to the Prime Minister and the Chancellor of Exchequer to impose to all public organisation the systematic production of management performance indicators. Value for money becomes the new iron law of the British public management and all policies must be judged in terms of cost-effectiveness”* (Faucher-King, Le Galès, 2007, p. 63⁷).

Tiago Moreira has also proposed a very clear overview of the British health care system, especially the role the “Market” is supposed to play in this organisation. First of all, he points out that all economic devices or ideas that have been used to reform the health care system question the relationship between health economics and health care organisation. He especially notes the importance of Qalys in the regulation system. The Qalys I will present further embody the articulation of the health economic and the equipment of public policies. The second point Tiago Moreira insists on is the importance of the logic of preference to understand the cost per Qalys measure. *“While individuals should be concerned with their particular situation, decision makers had to take decision on an aggregate level”* (Moreira, 2012, p. 73). Qalys are what permit to decide in a context of scarcity and to establish priorities. Third, the Qalys are not considered as rigorous scientific devices especially because of the institutional and political role they have been assigned: a decision support for the NHS. This is what Tiago Moreira calls the *“weak programme of health economics”*. *“While the strong programme emphasised the principles of economic theory and resource scarcity as central problems in health care, the weak programme focused on developing tools that to help decision-makers and the argument that more efficiency in health care was achievable”* (Moreira, 2012, p.

⁶ Liisa Kurunmäki and Peter Miller have also worked on the risk for public health systems to be systematically evaluated through economic calculation (Miller, Kurunmäki, 2011).

⁷ My translation.

75). While it could appear as a weakness of the calculation and therefore of the State's metrology, this hybrid aspect of the Qalys does not seem to be denounced by the private actors, which rather accept it and takes part to international forums to discuss and improve the methodology (for example the International Society for Pharmacoeconomics and Outcomes Research - IPSOR). For their part, even if they are not completely satisfying, public authorities consider that Qalys permit to reduce uncertainty.

How does the cost per Qalys work? The first part of the mechanism rests on a survey named EQ5D, which evaluates the quality of life of patients who are under treatment. As Euroqol, the company which has develop this tool explains it on its website, "EQ-5D is primarily designed for self-completion by respondents and is ideally suited for use in postal surveys, in clinics and face-to-face interviews. It is cognitively simple, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire"⁸. The simplicity of the survey can probably be considered as its asset. It supposes indeed that the patients can fulfil it during the usual interactions with physicians. To do so, questions have to be clear.

"The principle of the questionnaire is quiet simple. It is more complicated after. In clinical research the patient takes part to a random trial so they are frequent interactions with clinicians to evaluate the state of his tumour or his health status. We take this opportunity to add a questionnaire "quality of life" at this moment. The EQ-5D is really easy to use. It is just five questions. You just have to check five boxes and it establish your health status. Someone who has a lot of difficulties to dress, who is extremely anxious, etc., compares to someone who does not have all these difficulties, it will be easy to evaluate it. Then you are able to position these patients in a global population to see what value you give to these health statuses. And it lead you to define utility coefficient".⁹

⁸ Website of Euroqol: <http://www.euroqol.org/about-eq-5d.html>

⁹ Interview with a health economist in a Cancer Centre, January 2016.

<p>Under each heading, please tick the ONE box that best describes your health TODAY.</p> <p>MOBILITY</p> <p>I have no problems in walking about <input type="checkbox"/></p> <p>I have slight problems in walking about <input type="checkbox"/></p> <p>I have moderate problems in walking about <input type="checkbox"/></p> <p>I have severe problems in walking about <input type="checkbox"/></p> <p>I am unable to walk about <input type="checkbox"/></p> <p>SELF-CARE</p> <p>I have no problems washing or dressing myself <input type="checkbox"/></p> <p>I have slight problems washing or dressing myself <input type="checkbox"/></p> <p>I have moderate problems washing or dressing myself <input type="checkbox"/></p> <p>I have severe problems washing or dressing myself <input type="checkbox"/></p> <p>I am unable to wash or dress myself <input type="checkbox"/></p> <p>USUAL ACTIVITIES (e.g., work, study, housework, family or leisure activities)</p> <p>I have no problems doing my usual activities <input type="checkbox"/></p> <p>I have slight problems doing my usual activities <input type="checkbox"/></p> <p>I have moderate problems doing my usual activities <input type="checkbox"/></p> <p>I have severe problems doing my usual activities <input type="checkbox"/></p> <p>I am unable to do my usual activities <input type="checkbox"/></p> <p>PAIN/DISCOMFORT</p> <p>I have no pain or discomfort <input type="checkbox"/></p> <p>I have slight pain or discomfort <input type="checkbox"/></p> <p>I have moderate pain or discomfort <input type="checkbox"/></p> <p>I have severe pain or discomfort <input type="checkbox"/></p> <p>I have extreme pain or discomfort <input type="checkbox"/></p> <p>ANXIETY/DEPRESSION</p> <p>I am not anxious or depressed <input type="checkbox"/></p> <p>I am slightly anxious or depressed <input type="checkbox"/></p> <p>I am moderately anxious or depressed <input type="checkbox"/></p> <p>I am very anxious or depressed <input type="checkbox"/></p> <p>I am extremely anxious or depressed <input type="checkbox"/></p>	<div style="text-align: right;">The best health you can imagine</div> <div style="text-align: right;">100</div> <div style="text-align: right;">95</div> <div style="text-align: right;">90</div> <div style="text-align: right;">85</div> <div style="text-align: right;">80</div> <div style="text-align: right;">75</div> <div style="text-align: right;">70</div> <div style="text-align: right;">65</div> <div style="text-align: right;">60</div> <div style="text-align: right;">55</div> <div style="text-align: right;">50</div> <div style="text-align: right;">45</div> <div style="text-align: right;">40</div> <div style="text-align: right;">35</div> <div style="text-align: right;">30</div> <div style="text-align: right;">25</div> <div style="text-align: right;">20</div> <div style="text-align: right;">15</div> <div style="text-align: right;">10</div> <div style="text-align: right;">5</div> <div style="text-align: right;">0</div> <div style="text-align: right;">The worst health you can imagine</div> <p>1. We like to know how is your health today.</p> <p>2. This scale is marked from 0 to 100.</p> <p>3. 100 means the best health you can imagine. 0 means the worst health you can imagine.</p> <p>4. Mark an X on the scale to indicate how is your health today.</p> <p>5. Now, please note the number you marked on the scale in the box below.</p> <p style="text-align: center;">Your Health Today = <input style="width: 50px; height: 20px; border: 1px solid black;" type="text"/></p>
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Figure 1 – The EQ-5D survey constitutes the base of the cost per Qaly calculation. It is the « qualitative » part of the device.

The benefit in terms of quality of life is therefore measured by this questionnaire given to all patients in the trial¹⁰. The final score is between 0 and 1. The number 0 expresses the death while the number 1 expresses a perfect status of health. This is how a pharmaceutical company can say for example that its drug offers a gain of 0,46 Qalys¹¹. But this measure has to be reported to another amount: the cost of the product itself. And it is the moment when things become more complicated because the term “cost” often tends to substitute the term “price”. The company has to present the gain in Qaly but also the cost of the treatment in comparison to others. The “cost” include the “price” the company wants for its drug but also the cost of administration, transport and of medical support (that is to say the other treatments that are rendered necessary because of the administration of this drug).

The “cost per Qalys” tool is therefore the articulation of two devices: a qualitative one (the EQ-D5 – but one has to notice that it supposes a translation from a qualitative appreciation – the health status – to a quantitative one – the score of the questionnaire and the scale) and a quantitative one (the cost accounting). But the political technology is not yet complete. They are indeed completed by a third component: the rule that defines the way it has to be used. The NICE has decided to set up a threshold to define if a drug should or should not be reimbursed. For usual drugs the threshold is set at £20,000-£30,000 (NICE, 2008). The threshold plays a very important political role in the definition of the health care system. It defines what the society is able to accept in terms of price. Of

¹⁰ For example all patients who were the trial “TH3RESA” for the Trastuzumab emtansine have fulfilled a survey (see the 2nd part of this communication). There has been another trial: EMILIA.

¹¹ It is the case of the Trastuzumab Emtansine (while the French Agency presents the number of 0,45 -Rapport de la HAS, p. 5).

course, such a sentence is problematic. First of all it supposes that the NICE embodies the “society” and the citizens willing to pay. Secondly it implies that the prices presented by the industrial companies are justified. The threshold embodies the “critical value” (Grosse, 2008) a health care system can endure.

The threshold can be considered in two different ways. First it can be analysed as a tool of government that make efficiency prior to health care. Even if a drug works, if it is not effective enough the NHS wont accept it because of its “price”. In this view cost per Qaly threshold fit with the image of an austere system or what Jean-Paul Vernant calls “*a relatively strict health care system*”. But austerity does not mean that the British health care system could be called a “neoliberal system”. The reason why the NHS is not neoliberal is that if it refuses to accept a drug because it is not cost effective, the “market” or individuals will not be in position to obtain it. Rather than a “marketization” of the health care system, it seems more appropriate to use the term “economicization” (Benamouzig, 2005). The regulation of hospitals has proved it: the place and the role of the public authorities does not diminish but is reconfigured. It is the same for drugs policy. Secondly the threshold can be seen on the contrary as a tool that reinforce the administrative capacity of the State to negotiate with the pharmaceutical companies.

The cost per Qalys methodology is therefore a hybrid tool between the rational calculation and the government device. To analyse this tool one has to consider the rule that has been attached to it: the use of the threshold which implies a form of automaticity that could suggest a “depolitization” of the choices in terms of drugs reimbursement. I argue that the cost per Qaly threshold constitutes nevertheless a political tool that permit to the NHS to negotiate more strongly with the pharmaceutical industries.

2) State calculations and the challenge of new cancer drugs prices

For more than one decade, the cost of cancer has become a major issue for Welfare States. It is especially the case in the European countries. Numerous studies in health economics discuss the cost of this disease. Consider for instance a recent study published in *The Lancet Oncology*. In the introduction to the issue, Gary H. Lyman, professor of Medicine at the Duke University School of Medicine, writes: “*Implementation of high-quality cancer care is difficult without a thorough understanding of the total burden of the disease and the resources needed to provide appropriate care*” (Lyman, 2013). Many other research works have addressed the question of the cost of cancer and/or its economic consequences for health care systems. Scholars have focused for example on the impact of scientific progress on the increasing cost of cancer care. In an article published in 2007, Neal J. Meropol and Kevin A. Schulman emphasize the necessity of debating on the cost of cancer as it is calculated and as it should be calculated. They notice that this cost is not self-evident and that some elements are difficult to take into consideration. They write that “*the direct cost of cancer care include diagnostic tests, hospital and physicians fees and the cost of drug therapy*”. But the cost of drug is not easy to calculate. Indeed, it is not only the price of drugs that counts but also the cost of research and development. They conclude that the “*oncology profession*” has to work on the definition of best practices and to “*exert a positive influence on the economics of health care*” (Meropol, Schulman, 2007).

One of the most important issues of the “cost of cancer” is currently the “cost” of innovative treatments called targeted therapies. This increase of price is mostly due to the

arrival on the market of these drugs. Peter Keating and Alberto Cambrosio have given a clear explanation of what these therapies are by studying the history of the trial of one of the most famous drugs: the Glivec®. The interaction of oncogenetic and targeted therapies constitutes a “new biomedical domain” since the 1980. As they write it: *“The twenty years running from the isolation of the first human oncogene in 1984 to the decoding of the human genome at the beginning of the twenty-first century changed the entire face of cancer research by carrying the level of investigation from the cellular to the subcellular level”* (Keating, Cambrosio, 2012, p.304). The Glivec constitutes the incarnation of targeted therapies especially because of its impressive results for the Chronic myelogenous leukemia (Tursz, 2014). There are today around 60 drugs that can be classified as targeted therapies.

Another notable case is the Kadcyla®. The study of this drug appears quiet heuristic since it allows to observe a disagreement on the evaluation of the NICE and a metrological controversy between the public agencies in charge of the evaluation and the pharmaceutical company Roche. Even if this controversy appears as confined and extremely technical, it reveals the importance of cost per Qalys as an administrative tool and more precisely a calculating capacity when the State has to face private interest groups. The Kadcyla® has been evaluated by the NICE but has not been considered as effective enough. In the report of the NICE, one can read: *“Trastuzumab emtasine costs £1624,01 per 100mg vial and £2625,62 per 160mg vial. The company estimated that the average cost of a course of treatment with trastuzumab emtasine is £90,831 (excluding administration costs), assuming a 3-weekly dose of 3,6 mg/kg”*. The cost per Qaly in the case of the Kadcyla® depends on the combination of the treatment with another drug. Nevertheless it is at least £90,000 per Qaly. If the threshold for cancer drugs is £50,000 there is therefore no chance for this drug to be reimburse.

But the NICE is of course at the heart of disputes engaging simultaneously principles of justice and technical matters. In his study about the Alzheimer’s Drugs Alliance Tiago Moreira points out the uncertainty in the calculation of Qalys concerning anti-dementia drugs. He proposes to *“understand the relationship between knowledge practises and political process in setting rationing standards”* (Moreira, 2011, p. 1333). My inquiry on the cancer’s economy clearly takes this question into account but I propose to explore more specifically the articulation of economic calculation in cancer on the one hand and the consistency of the public decision process on the other hand. That is to say there are multiple arrangements between knowledge production and knowledge uses in public policies on cancer care. The economic regulation of drugs is far from being evident. *“NICE’s consultation processes are suggestive of a preference for a ‘public dialogue’ model of the governance of knowledge in health care. However, in the case of dementia, as with cancer drugs and multiple sclerosis, discussions breached the institutional and knowledge boundaries of such a model. Stakeholders publicly challenged NICE’s technological appraisal”* (Moreira, 2011, p. 1339). The case of new cancer drugs is one of these challenge: how the National Health Service could refuse the access to a treatment that could increase survival time? If the NHS considers drugs have to be efficient it also has to provide care. It is of course extremely complicated for the national health organisation to refuse some treatments especially when some reports tend to indicate that the survival rates is lower in United Kingdom than in others countries (Coleman et al., 2011).

3) The invention of the Cancer Drugs Fund: A “Political Stunt”?

If the targeted therapies present most of time an inefficient result in terms of cost per Qalys they are considered as exceptional product that should be refused but are nevertheless wanted especially by the patients organisation. Therefore, for exceptional drugs the NHS has invented an exceptional Fund. “Exceptional” has two meaning. It means that it has to pay for drugs that cannot be evaluated with the usual tools but it also means that the Fund must be temporary until a solution is found with the pharmaceutical industries. The Cancer Drugs Fund has been created in October 2010. But indeed, some actors also present it as a temporary solution. It is the case of the Breast Cancer Care, a patient’s organisation in UK. In one of its reports, we can read that *“there have been a number of drugs, in particular for secondary breast cancer, which have not been recommended by NICE because they were deemed to be too expensive to provide routinely. To go some way in addressing this problem, the Cancer Drugs Fund was created to give patients in England access to some of the more expensive cancer drugs not recommended by NICE for routine use. It was originally intended to be a temporary way for people to access cancer drugs while a longer-term solution to the problems of accessing expensive drugs, including reforming NICE’s processes, could be found”*¹². The temporary solution has finally been renewed and still exists. There are today more than 30 drugs or indications that are considered as not cost effective by the NHS and that are in the CDF.

At the end of the 2000 the problem becomes more and more present in the public debate. Is it possible to refuse to an English patient a drug that would be given to a French patient? During the general election campaign in 2010, the conservative candidate David Cameron promised to find a solution for paying these drugs that are not cost effective enough and to create a Cancer Drugs Fund. Two years later, in his speech at the Conservative conference, he says:

“To meet the challenges our country faces, we must have confidence in ourselves... confidence as a party. We’ve been in office two and a half years now – and we’ve done some big, life-changing things. Just ask Clive Stone, who you saw in a film earlier. I met him years ago, when we were in Opposition. He had cancer and he said to me: the drug I need – it’s out there but they won’t give it to me because it’s too expensive ...please, if you get in, do something about it. And we have. A new cancer drugs fund that has got the latest drugs to more than 21,000 people and counting. There was a reason we could do that. It’s because we made a big decision to protect the NHS from spending cuts”.¹³

While UK is famous for its strong capacity to evaluate cost-benefits the creation of the CDF seems to constitute the failure of the NICE’s severity. The role-played by industrials like Roche and Patient’s associations is central to understand the creation of the CDF. Therefore it means that even the British system has not resist to the assaults of the Pharmaceutical industry. The Cancer Drugs Fund can be defined as a mechanism supposed

¹² Consultation on the new Cancer Drugs Fund model, Breast Cancer Care, December 2015, https://www.breastcancercare.org.uk/sites/default/files/files/text_cancer_drugs_fund_easy_read_guide_v6.pdf

¹³ David Cameron’s conservative party conference speech, October 2012. Online: <http://www.telegraph.co.uk/news/politics/conservative/9598534/David-Camerons-Conservative-Party-Conference-speech-in-full.html>

to correct the imperfection of the regulation by the NICE and the principle of the cost-effectiveness threshold but which is in the same time itself an imperfect mechanism that is likely to be temporary and which is likely to end. It embodies the problem public authorities are confronted with in terms of cancer care: how to finance products that seems not financeable? The CDF is therefore a political, electoral, economical, scientific object. A British health scientist says:

“The scheme was partly a product of sustained advocacy by patient groups, supported by companies such as Roche who have been one of the main beneficiaries. You will note that in the year prior to the election fund expenditure rose considerably!”¹⁴

This view of the origin of the CDF is quiet accepted by numerous of specialist of the health care system. David Colquhoun a pharmacologist at the University College London claims in 2014 on television that the CDF *“is a political stunt in response to shroud-waving by big pharma companies”*. When the journalist asked him if he thought that the pressure on David Cameron was the main explanation, he answer then *“yes, and the pressure is enormous. It is brought by the companies themselves but it also brought by patient organizations”¹⁵*. Eric Low, the chief executive of Myeloma UK also explains *“We know that the Cancer Drugs Fund was a sticking plaster policy probably to get vote and look popular”¹⁶*.

What also matters is the functioning of the CDF. A commission in the CDF called “the Fund Panel” is in charge to decide which drug fulfils the conditions for being reimbursed¹⁷. A report of the National Audit Office mentions that between April 2013 and December 2014, 26 drugs have been approved on 65 submitted. It means that 60% of the drugs have been refused. But, have the governments reported the problem of the efficiency of cancer drugs? Is the CDF the sign that Public Health is still as important as the cost-effectiveness principle? The National Audit Office has published in 2015 a very important document to understand the questions the CDF raises for the British health policy. One can read that *“all parties agree that the Fund is not sustainable in its current form and the NHS England is developing proposals for reform. The Fund was intended as a temporary measure until the government put in place a new pricing system when the existing Pharmaceutical Price Regulation Scheme expired in 2013”* (NAO, 2015, p. 8)¹⁸. The results of the CDF are not minors: between 2011 and 2015, more than 77 000 patients have been treated with a drugs thanks to the CDF and the number of patients that have access to one of these treatments increases by 30% each year (NAO, 2015, p.16). The success of the Fund is ironically the sign of a fail on the other part of the health care system. Moreover, this success is also a serious problem for public authorities, which try to contain public expenditures and which have therefore created an exceptional mechanism that tends to permit a growth of health expenditures.

¹⁴ Interview of a professor of Health Sciences, 2016.

¹⁵ <https://www.youtube.com/watch?v=7SayJ2cwYok&nohtml5=False>

¹⁶ https://www.youtube.com/watch?v=Hqv16lk-7_Y

¹⁷ I plan to investigate this Panel by studying the case of one controversial drug : the Kadcyla.

¹⁸ A part of this research on the CDF will consist in studying the production of this new pricing payment system.

Cost of the Cancer Drugs Fund						
	2010-11	2011-12	2012-13	2013-14	2014-15	Total
Cost (£m)	38	108	175	231	416	968
Budget (£m)	50	200	200	200	280	930
Cost as a percentage of allocated budget (%)	77	54	88	115	148	104
Notes						
1 Costs are rounded to the nearest £ million.						
2 Data for 2010-11 represent in-year funding provided by the Department of Health in October 2010.						
Source: National Audit Office analysis of Department of Health data and NHS England data						

Figure 2 - The cost of exception. The National Audit Office published a report in September 2015 on the Cancer Drugs Fund. In this figure one can observe the amount dedicated to the regulation of cancer treatments that are not eligible to the NHS routine.

The NAO has also tried to estimate the cost of the CDF. Ironically, while the Fund is hardly criticized by numerous economists it seems to be also a real success when one looks at the increase of the patients it supports and the number of drugs it reimburses. The NAO notes that the Fund budget has been growing almost each year: £50 millions in 2010, £200 millions in 2011, 2012 and 2013, £280 millions in 2014 and £340 millions in 2015 (NAO, 2015, p. 29).

Our inquiry focuses on targeted therapies. What part of the CDF do these drugs concern? And why are these drugs in the Fund and not in the usual NHS system? One part of these drugs concern rare cancers. They have fewer chances to be considered as cost-effective because of the low number of patients that could be cured. There is therefore clearly a fail of the mechanism put in place by the NHS. 70% of the drugs indications are for rare cancers (NAO, 2015, p. 22). But if the majority of drugs are for rare cancers, the majority of patients treated through drugs financed by the Fund are concerned by common cancers such as colorectal, breast and prostate cancers and “the most common, Avastin (Bevacimuzab), accounted for almost one fifth of the patient patients supported by the Fund over the two years” (NAO, 2015, p. 22). But despite the exceptional principle of the Fund the idea of an efficient use of the public money does not disappear from the mind of the regulator. The NAO exposes therefore that it would be important the Fund presents results in terms of quality and justifies the expenditures and their growth. “In January 2015, we reported that these gaps in data made it difficult to evaluate in a meaningful way the money spent through the Fund” (NAO, 2015, p. 26). While the Fund has been created because the usual way to evaluate drugs cost-effectiveness, the authors of the reports ask anyway for an evaluation of the money the Fund has spent.

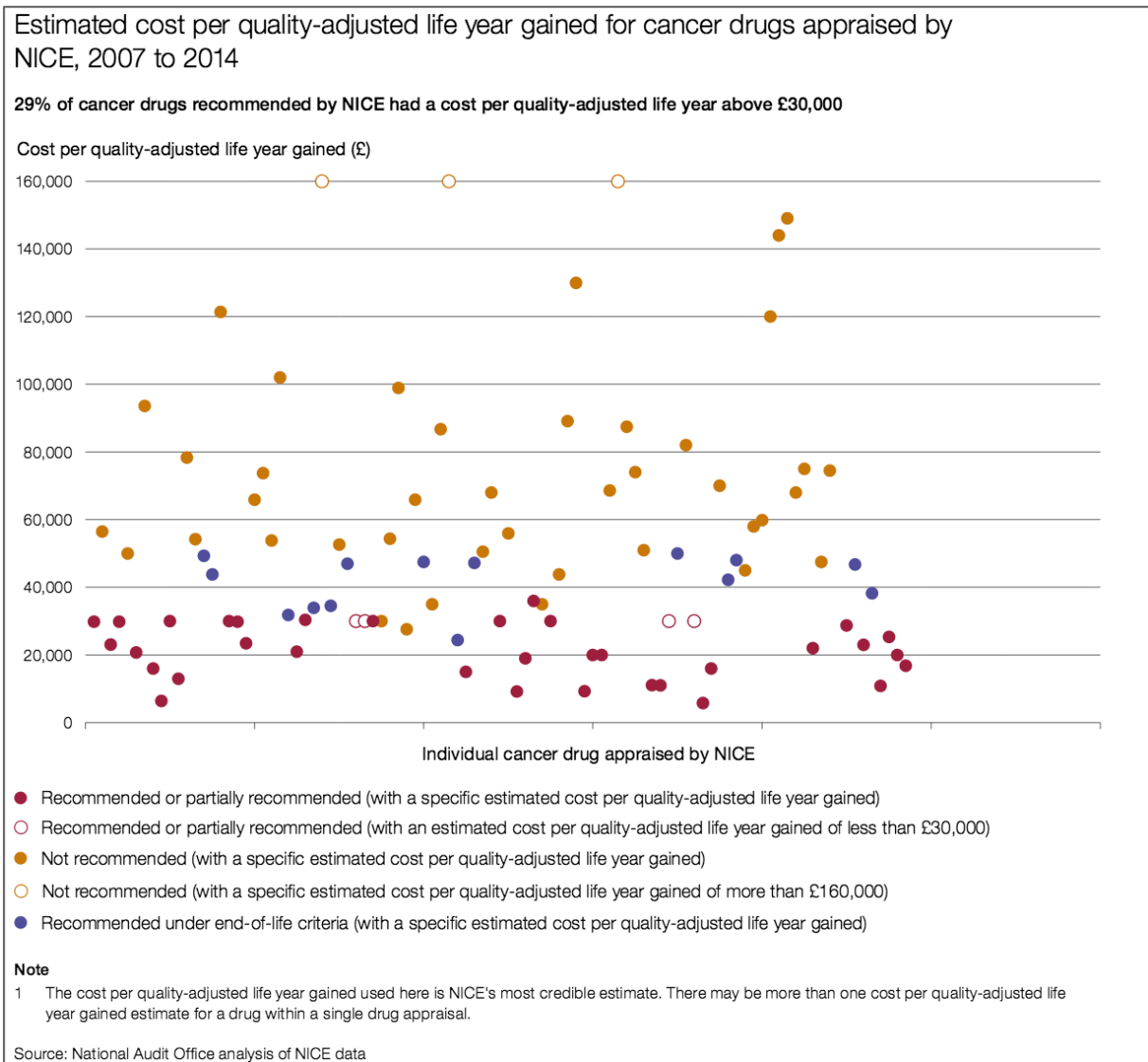


Figure 3 - A space of comparison. The different level of cost per QALY of the cancer drugs appraised by NICE.

The CDF appears as a temporary solution to a more general problem: the capacity of the cost per Qaly's threshold to determine the frontier between efficient and too expensive drugs. Therefore, the CDF does not respond to this problem but sweep the problem under the carpet: the adequacy of the Cost per Qaly's threshold. The NAO notices for example that "Some cancer charities and pharmaceutical companies told us that they think NICE's cost-effectiveness thresholds do not adequately reflect the value society places on treating cancer patients, and that the thresholds hinder improving or extending end-of-life care for people with terminal conditions" (NAO, 2015, p. 13). The audit mission points out the strong relationship between the action and the modalities of decision of the NICE and the treatments the Cancer Drugs Fund is likely to pay for. As they write, "the number of drugs that potentially could be accessed through the Fund is therefore affected by the number of cancer drugs that NICE appraises, the time NICE takes to appraise cancer drugs, and whether NICE recommends cancer drugs for routine NHS commissioning" (NAO, 2015, p. 13).

The report presents clearly the mechanism of the Fund even how a patient can have access to it and asking for a drug reimbursement. But as all official reports it also encapsulates all forms of controversies concerning the Fund. For example it appears important to question the institutional and political origin of the Fund and the consequences it has implied on the functioning of this organisation. An English professor of epidemiology who has studied the way cost-effectiveness is calculated and the role played by pharmaceutical industries in the pricing process explains:

“The reason the Fund was created was, this is my understanding, that the cancer drugs do not obey the rules, they were not cost-effective. You cannot evaluate them to the normal system. Even if they were not cost effective, the government want to respond the pressure from charities or companies to give some access to people who are dying of cancer, on a sort of compassion to give some person a chance. What happens then was that the original purpose might have been forgotten and the number of drugs in the CDF gradually increased and they have created a monster.”¹⁹

The Cancer Drugs Fund articulates different dimensions that are inextricable: the economic necessity to regulate the pricing process of expensive drugs; the institutional role played by interest groups; the specific context of general election in 2010; the controversy about the effectiveness of some treatments.

4) Revival or standstill of the British Welfare State?

The case of the Cancer Drugs Fund questions the capacity for the State to encapsulate objects like disease's treatment in economic calculation. It also questions the capacity of the State to resist to interest groups especially pharmaceutical industries. While there is a market of targeted therapies, it remains quiet singular as it implies a visible intervention of the public authorities. The fundamental dilemma of the NHS is that it cannot in theory accept that drugs exceed the cost per Qaly threshold but it can also not refuse to provide a drug that has a minimum efficiency. The David Cameron's speeches are a clear embodiment of this dilemma. How then to deal with an immoral economy and how can a State preserve its capacity to cure people with the latest technologies available? In another words: *how can a State preserve its health sovereignty in front of an immoral economy?* Two main points have to be noticed. First of all the study of the Cancer Drugs Fund allows an analysis of the way economic calculation defines (partly) the State itself. Second, it leads us to question the political meaning of a “political stunt” or what we could call an institutional exception. Does the CDF embody a revival of the Welfare State or its standstill?

The definition of the State is indeed at stake. While it has been converted since the 1980's into both a welfare entity and a calculator actor, it has tends to be more or less one of this aspect. With the increase of new cancer drugs, the British State has faced a political and economical dilemma: curing and being cost-effectiveness or curing no matter what. In a way the creation of the Cancer Drugs Fund appears as a revival of the sovereign Welfare State, as it presents itself as able to pay for all cancer drugs. But in another way, this sovereignty is diminished by the action of pharmaceutical industries that have obliged the

¹⁹ Interview with a Professor of epidemiology, February 2016.

NHS to change the rules it has promoted to provide cost-effectiveness care. The process of equipment by the State of economic calculation to face the private organisation is interrupted because of the impossibility to refuse treatment that could improve survival of the patient.

In terms of public policy analysis, we have also to study the specificity of the solution proposed by the British healthcare system: a temporary Fund. What does it mean that a national healthcare system deploys a tool that supposes to deny the usual way to define the rules concerning the reimbursement of drugs? What does it mean that, to preserve the capacity of the system to provide drugs even if they are expensive, the State has to renounce to a form of regulation? These are all the questions I wish to focus on in my inquiry on the CDF.

Conclusion

The materialization of the willing to pay takes different forms in terms of health care expenditures. One of these forms consists in a threshold that is to say an economic, political and institutional border that drugs should not overpass if they want to be reimbursed by the public authorities. The argument we make about the CDF and the calculation of the threshold of cancer treatment is that it embodies the double face of contemporary public policy in terms of health care expenditure. On the one hand, these expenditures have to be strictly regulated and governed by mechanisms as a threshold which defines the level the State accept to pay for one treatment and on the other hand the health care system supposes expenditures that are not likely to be encapsulated in the economic calculation because their efficiency can not be considered as good enough but although as a relevant criteria for not reimbursing them. The threshold politics reveals the magnitude of the constraint of the economic calculation in the public policies in terms of struggle against cancer.

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